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ELANCO ANIMAL HEALTH

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ANIMAL LEGAL DEFENSE FUND, FOOD & WATER WATCH, and FOOD ANIMAL CONCERNS TRUST,

Plaintiffs,

v.

ALEX AZAR, Secretary of the United States Department of Health and Human Services; STEPHEN HAHN, Commissioner of the United States Food and Drug Administration; and UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

Civil Case No. 3:20-cv-03703-JCS

ELANCO ANIMAL HEALTH'S MOTION TO DISMISS FOR LACK OF ARTICLE III STANDING AND FAILURE TO EXHAUST ADMINISTRATIVE REMEDIES

Date: January 14, 2021
Time: 1:30 p.m.
Dept: San Francisco, Courtroom 3
Judge: Hon. Richard Seeborg

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NOTICE OF MOTION

Please take notice that on January 14, 2021, at 1:30 p.m., or as soon thereafter as the matter may be heard before the Honorable Richard Seeborg, United States District Judge, in Courtroom 3 of the United States Courthouse, 450 Golden Gate Avenue, San Francisco, California 94102, Intervenor-Defendant Elanco Animal Health ("Elanco") will, and hereby does, move the court for an order dismissing the First Amended Complaint filed by Plaintiffs Animal Legal Defense Fund ("ALDF"), Food & Water Watch ("FWW"), and Food Animal Concerns Trust ("FACT") (collectively, "Plaintiffs") for lack of Article III standing; failure to exhaust mandatory administrative remedies as required by the Administrative Procedure Act ("APA"), 5 U.S.C. § 704; and failure sufficiently to plead a claim for relief pursuant to Federal Rules of Civil Procedure 8 and 12(b)(6). In the alternative, Elanco requests that the Court stay this matter pending Plaintiffs' exhaustion of their administrative remedies, as required by Food and Drug Administration ("FDA") regulations and the APA.

POINTS AND AUTHORITIES

INTRODUCTION AND STATEMENT OF ISSUES

Asserting purported violations of the National Environmental Policy Act ("NEPA"), 42 U.S.C. §§ 4321, *et seq*., and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq*., Plaintiffs filed suit under the APA challenging FDA approvals of the animal drug lubabegron, which is administered to animals in feed and known under the trade name Experior. Plaintiffs claim that FDA's approvals of Experior should be vacated and all use of Experior barred until FDA conducts further reviews of Experior's safety, effectiveness, and potential environmental impacts.

Plaintiffs' lawsuit mirrors ALDF's prior challenge to FDA's approval of a different approved Elanco animal drug that is also administered in feed, ractopamine. The district court dismissed that complaint for failure to exhaust the citizen petition review procedures required by FDA regulations, *see Ctr. for Food Safety v. Hamburg*, 142 F. Supp. 3d 898 (N.D. Cal. 2015), and, on appeal, the Ninth Circuit directed ALDF "to comply with the FDA's citizen petition requirement" before proceeding in court, *Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 304

(9th Cir. 2017). But Plaintiffs here did not heed that instruction, and have proceeded with their claims in this Court without first exhausting FDA's citizen petition review procedures. *See* 21 C.F.R. § 10.25(a); *id*. § 10.45(b). The doctrine of administrative exhaustion therefore precludes judicial review of Plaintiffs' claims until Plaintiffs comply with the administrative procedures mandated by FDA's regulations.

Plaintiffs' claims should also be dismissed on two additional, independent grounds. *First*, Plaintiffs' claims should be dismissed for lack of Article III standing. To have standing to sue, Plaintiffs must plausibly allege (and ultimately prove) that they suffer a cognizable injury that is fairly traceable to FDA's alleged statutory violations, and likely to be redressed by an order from this Court vacating approval of Experior. *See*, *e.g.*, *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102–03 (1998). Reflecting the fact that Experior is not yet on the market, Plaintiffs' Amended Complaint asserts only future injuries that could occur *if* Experior becomes available for sale, *if* feedlot operators then use Experior in ways that result in discharges into the environment, and *if* those discharges adversely affect Plaintiffs' members. Because those hypothetical injuries rely on lengthy, speculative chains of causation, they are insufficiently imminent to satisfy Article III's requirements. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Plaintiffs' FDCA and NEPA claims must therefore be dismissed.

Plaintiffs' NEPA claims further fail to satisfy Article III's causation and redressability requirements. Because Plaintiffs' alleged environmental injuries from the future discharge of Experior at industrial cattle feedlots hinge upon regulatory actions (or inaction) of the Environmental Protection Agency ("EPA"), Plaintiffs' challenge to FDA's NEPA review lacks the causal and remedial connections necessary to satisfy Article III.

Second, Plaintiffs' challenge to FDA's denial of ALDF's petition for an administrative stay ("Stay Petition") should be dismissed for failure adequately to plead a claim for relief. Federal Rules of Civil Procedure 8 and 12(b)(6) require a plaintiff to set forth both the legal theories and relief requested for each claim asserted in a Complaint. Plaintiffs' contention that FDA improperly denied ALDF's Stay Petition, however, alleges only that the denial provides Plaintiffs an exhausted final agency action subject to judicial review, *see* First Am. Compl.

("FAC") (Dkt. No. 30), First Claim for Relief, ¶¶ 4, 6, not that any relief—either vacatur of the denial decision or a stay of the effective date of Experior's approval—is due for the alleged legal violation. Absent an appropriate request for relief, the claim cannot proceed.

Viewed collectively and individually, Plaintiffs' claims are legally deficient, and should be dismissed. In the alternative, the Court should stay this litigation "to allow [Plaintiffs] to comply with the FDA's citizen petition requirement." *Ctr. for Food Safety*, 696 F. App'x at 304.

STATEMENT OF FACTS

Plaintiffs challenge FDA's approval of New Animal Drug Applications ("NADAs") for Experior, a drug approved for use in cattle alone and in combination with certain antibiotics, that reduces ammonia gas emissions in animals' waste. FAC ¶¶ 1, 4, 12; *see also* Declaration of Karen Smith, Ph.D (Dkt. No. 18-1), ¶ 4. Plaintiffs allege that FDA approved Experior without following NEPA's procedural requirements for review of potential environmental impacts, and without adequately determining Experior's safety and effectiveness in its target animals as required by the FDCA. *See*, *e.g.*, FAC ¶ 2.

Plaintiffs first allege that FDA's environmental analysis of Experior's future use violated NEPA by failing to account for "poor manure management conditions" and EPA's "underregulat[ion]" of concentrated animal feeding operations ("CAFOs") where Experior may be used. *Id.* ¶ 154. Plaintiffs contend that, while FDA disclosed the possibility that Experior may enter the environment through land application of manure and corresponding runoff, FDA did not consider "several known risks of environmental contamination due to CAFO manure management practices that will enable Experior to permeate the environment." *Id.* ¶¶ 149–50. In Plaintiffs' view, NEPA requires FDA to consider, among other things, that "manure can be stored in unlined lagoons that are susceptible to leakage, overflow, or rupture, any of which could lead to groundwater and soil contamination" and that "uneaten medicated feed" may also contaminate groundwater and soil. *Id.* ¶ 150. Taken as whole, Plaintiffs allege that FDA's approvals of Experior "exacerbat[e] the existing animal, public, and environmental health effects of the CAFO industry." *Id.* ¶ 120.

Plaintiffs further assert that FDA's approval of Experior—which Plaintiffs recognize has not yet become available in the marketplace, *see id.* ¶ 33—has injured their members and supporters. *See id.* ¶¶ 19–35. According to Plaintiffs, some of their members "live, work, and recreate near and downstream from cattle feedlots that *may* give their cows Experior." *Id.* ¶¶ 19, 26, 28, 30 (emphasis added). Plaintiffs contend that their members are "concerned" that there is a "risk that Experior will migrate from feedlots and contaminate waterways and groundwater," *id.* ¶ 20, and that their members' enjoyment of the environment is therefore "diminished by their concern and the increased risk of harm Experior presents for wildlife and their habitat," *id.* ¶ 21. To contend with this concern, Plaintiffs allege that some of their members have altered or will alter whether and how they use the waterways. *See, e.g.*, *id.* ¶¶ 21–24. For example, Plaintiffs assert that one ALDF member enjoys boating on the Mississippi River "but is hesitant to engage in other activities such as kayaking and swimming in the river in the future because these activities involve being in contact with the river and therefore more exposed to Experior." *Id.* ¶ 24. Similarly, Plaintiffs allege that a FACT member who lives near Lake Michigan currently "avoids swimming in the waterway due to concerns about the health impacts of contaminants" and his "knowledge that feedlots near Lake Michigan may begin to use Experior heightens his concerns and would lead him to avoid swimming even if other more easily detectable contaminants in the waterway decrease." *Id.* ¶ 31. And Plaintiffs contend that a FWW member who enjoys visiting conservation areas in Idaho has already "paused plans to purchase a paddleboard to use on waterways near her because of her concerns about direct exposure to Experior-contaminated water downstream." *Id.* ¶ 28. Plaintiffs assert that the member "will be even more apprehensive to invest in this activity," "[i]f Experior [is] released into these waterways." *Id.*

Plaintiffs also assert that their members are "concerned" about the human health impacts of consuming beef from cows that may be treated with Experior. *See, e.g.*, *id.* ¶¶ 22–24, 26–27. "To alleviate their concerns," Plaintiffs say their members "will be forced to source and consume beef that is raised without Experior" and they "will pay premiums to purchase beef raised without Experior" or will "simply be unable to find and source beef that is raised without Experior." *Id.* ¶ 22.

Plaintiffs further allege that FDA's approval decisions violated the FDCA by relying on studies that are, in Plaintiffs' estimation, inadequate to assess Experior's safety and effectiveness in target animals. *Id.* ¶¶ 132–48. In particular, Plaintiffs contend that the studies relied upon by FDA "contained inadequate experimental conditions to simulate feedlots," "were based on small sample sizes," and "did not look adequately at biologically plausible and probable adverse events" such as "lameness and overheating." *Id.* ¶¶ 132–34. Plaintiffs also allege that FDA improperly "dismissed" other concerns about Experior's safety, and otherwise relied on studies allegedly marred by "a certain amount of data manipulation" regarding Experior's effectiveness. *Id.* ¶¶ 132–48.

Prior to filing this lawsuit, "Plaintiff ALDF submitted a . . . Petition for Stay" of FDA's "approval of NADA 141-508 for Experior and the corresponding" NEPA review documents because, in ALDF's view, "Experior has not been shown to be safe and effective," and Experior has "the potential . . . to cause significant harm to the environment . . . ." *Id.* ¶¶ 125–26. The other two Plaintiffs in this suit—Food & Water Watch and Food Animal Concerns Trust—did not join in ALDF's stay application and have not taken any action before FDA with respect to the claims they assert here.

On May 20, 2019, FDA denied ALDF's Stay Petition, concluding "that the Petition did not meet the conditions set out in 21 C.F.R. § 10.35(e) requiring issuance of a stay." FAC ¶ 128. The agency explained that "[d]uring the new animal drug review process, FDA thoroughly reviewed the NADA for Experior and determined the drug met the standards for approval under the [FDCA] and FDA regulations." FDA Denial Letter, at 3 (May 20, 2019).[1] Among other

[1] Both ALDF's Stay Petition and FDA's Denial Letter are available on the federal government's regulatory website. *See* Requests that the FDA stay approval of New Animal Drug Application 141-508 for Experior™ (lubabegron Type A medicated article) and the corresponding Environmental Assessment and Finding of No Significant Impact (Docket No. FDA-2018-P-4656), available at https://www.regulations.gov/docket?D=FDA-2018-P-4656 (last visited October 29, 2020). In reviewing a motion to dismiss, this Court "can consider exhibits attached to the Complaint or matters properly subject to judicial notice," as well as "documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the . . . pleading." *Hicks v. PGA Tour, Inc.*, 897 F.3d 1109, 1117 (9th Cir. 2018) (citations and quotations omitted). Plaintiffs' Complaint alleges the contents of ALDF's

things, FDA reasoned that ALDF's Stay Petition repeatedly failed to "provide any specific data or information in support of" its assertions that FDA inadequately considered the potential health or environmental effects of approving Experior. *Id*. at 9; *see also id*. (finding that Stay Petition "does not contain an explanation of, or support for, the concern" with food safety); *id*. at 10 ("The [Stay] Petition also asserts, without providing any support, that beta-agonists are 'known to increase aggression and hyperactivity in animals[.]'"); *id*. at 12 (Stay Petition's "assertion that the approval of Experior™ will lead to a denser packing of feedlots . . . is unsupported anywhere in the [Stay] Petition"); *id*. at 14 (finding "the [Stay] Petition failed to provide support for the assertion that the daily manure production number used in the Experior™ [environmental assessment] is underestimated").

More than a year after FDA denied ALDF's Stay Petition—and eighteen months after FDA's initial approval of the NADA for Experior—Plaintiffs filed the instant lawsuit. *See* Compl. (Dkt. No. 1). On September 29, 2020, Plaintiffs filed their First Amended Complaint. *See generally* FAC. In Plaintiffs' view, ALDF's "timely petition to stay exhausts administrative remedies," *id.*, First Claim for Relief, ¶ 4 (citing 21 C.F.R. § 10.45(c)), and "FDA's denial of . . . ALDF's [Stay] Petition . . . is final agency action subject to judicial review under the APA," *id*. ¶ 6 (citing 5 U.S.C. § 704). To remedy the allegedly unlawful approval of Experior, Plaintiffs ask this Court to (1) "[v]acate FDA's decision to approve Experior unless and until it complies with the FDCA, NEPA, and the APA"; and (2) "[i]ssue preliminary and permanent injunctive relief barring the use of Experior until FDA complies with the FDCA, NEPA, and the APA." *Id*., Request for Relief, ¶¶ 3–4.

Stay Petition and FDA's Denial Letter, and this Court may take judicial notice of government records and materials available on government websites. *See*, *e.g.*, *Banks v. Warner*, No. 94-56732, 1995 WL 465773, at *1 (9th Cir. Aug. 7, 1995) ("It is entirely proper for a court to take judicial notice of records and reports of administrative agencies."); *Ries v. Hornell Brewing Co.*, No. 10-cv-1139-JF, 2010 WL 2943860, at *5 n.3 (N.D. Cal. July 23, 2010) (concluding that document available on FDA website "is a matter of public record and is judicially noticeable").

On August 25, 2020, Elanco moved for leave to intervene in this matter to protect its interest in the approval of its NADA for Experior. Mot. for Intervention (Dkt. No. 18). The Court granted Elanco's motion on September 24, 2020. Order (Dkt. No. 25).

ARGUMENT

I. THE COURT SHOULD DISMISS PLAINTIFFS' CLAIMS FOR LACK OF ARTICLE III STANDING.

Standing is a constitutional prerequisite to the exercise of federal judicial power, and thus constitutes "an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). For a plaintiff to have standing, (1) "there must be alleged (and ultimately proved) an injury in fact—a harm suffered by the plaintiff"; (2) "there must be causation—a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant"; and (3) "there must be redressability—a likelihood that the requested relief will redress the alleged injury." *Steel Co.*, 523 U.S. at 102–03 (quotation marks omitted). Plaintiffs bear the burden of demonstrating Article III standing and must support each element of their standing "with the manner and degree of evidence required at [each] successive stag[e] of the litigation." *Lujan*, 504 U.S. at 561; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (explaining that, at the motion to dismiss stage, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face" (quotation marks omitted)). Further, because "standing is not dispensed in gross," *Lewis v. Casey*, 518 U.S. 343, 358, n.6 (1996), plaintiffs are required to establish standing for "each claim [they] seek to press," *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). Where, as here, organizations bring suit on behalf of their members, they must show that the members would have standing in their own right to sue. *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977).[2]

[2] An organization may also bring suit on its own behalf for injuries it has sustained. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 n.19 (1982). To do so, the organization must allege (and ultimately show) "frustration of its organizational mission" and "diversion of its resources to combat" the adverse effects of the challenged government action. *Smith v. Pac. Props. and Dev. Corp.*, 358 F.3d 1097, 1105 (9th Cir. 2004). Plaintiffs' First Amended Complaint makes no

Plaintiffs' claims for relief do not satisfy this foundational burden. As detailed below, Plaintiffs' alleged injuries are not cognizable because they are neither actual nor imminent. Moreover, for purposes of their NEPA claim, Plaintiffs' alleged injuries are neither fairly traceable to FDA's alleged NEPA violations in approving use of Experior, nor would they be redressed by an order from this Court vacating FDA's approvals and remanding them for further agency NEPA review. Because Plaintiffs have failed to demonstrate standing, their claims must be dismissed. *See*, *e.g.*, *Steel Co.*, 523 U.S. at 94.

A. Plaintiffs Have Not Plausibly Alleged Cognizable Injuries In Fact.

To establish injury-in-fact, a plaintiff must show "an invasion of a legally protected interest which is (a) concrete and particularized . . . and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560. "In environmental cases, courts must carefully distinguish between injury to the [plaintiff] and injury to the environment." *Ctr. for Biological Diversity v. U.S. Envt'l Protection Agency*, 937 F.3d 533, 537 (5th Cir. 2019). "Article III standing requires injury to the" plaintiff, "[i]njury to the environment is insufficient." *Id.* Although a cognizable injury may be linked to a plaintiff's interests—aesthetic, recreational, or scientific—in the environment, "such environmental interests cannot support an injury in fact unless they have been actually harmed or imminently will be." *Id.*

While "imminence is concededly a somewhat elastic concept," the Supreme Court has emphasized that "it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes." *Clapper*, 568 U.S. at 409 (quotation marks omitted). "By ensuring a future injury is not 'too speculative," the imminence requirement 'reduce[s] the possibility of deciding a case in which no injury would have occurred at all.'" *Ctr. for Biological Diversity*, 937 F.3d at 537 (quoting *Lujan*, 504 U.S. at 564 n.2). For that reason, mere "allegations of possible future injury are not sufficient." *Clapper*, 568 U.S. at 409 (brackets and quotation marks omitted). Instead, when a party's allegations of injury rest on future harm,

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allegation that any Plaintiff has diverted or anticipates diverting resources to counteract alleged effects of FDA's approval of Experior, so Plaintiffs have not established organizational standing.

standing arises only if that harm is "'certainly impending,' or there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper*, 568 U.S. at 409); *see also Nat'l Res. Def. Council v. EPA*, 735 F.3d 873, 878 (9th Cir. 2013) ("[A]n injury is 'actual or imminent' where there is a 'credible threat' that a probabilistic harm will materialize."). Plaintiffs' alleged injuries fail to meet the imminence requirement for at least three reasons.

First, Plaintiffs' theory of injury "stacks speculation upon hypothetical upon speculation, which does not establish an 'actual or imminent' injury." *N.Y. Regional Interconnect, Inc. v. FERC*, 634 F.3d 581, 587 (D.C. Cir. 2011). Plaintiffs acknowledge that Experior has not become available in the marketplace, *see* FAC ¶ 33, and do not allege that it will imminently enter the market or that a date has been set for Experior sales to begin. Nevertheless, Plaintiffs allege that FDA's approval of Experior will harm their members and supporters at some unidentified point in the future because they "live, recreate, and eat fish caught downstream from cow feedlots" and are "concerned" about "the risk that Experior will migrate from feedlots and contaminate waterways and groundwater."[3] *Id.* ¶ 20. Because of this "concern," Plaintiffs say their members will face diminished enjoyment of "seeing wildlife in areas downstream from cow feedlots," *id.* ¶ 21, and experience "fear" about the human health effects of swimming in or consuming animals from those waterways, *id.* ¶ 23. Plaintiffs assert that their members will "need to" conduct themselves differently to contend with these concerns—some will be "hesitant to engage in" activities such as swimming in waterways near cow feedlots, *id.* ¶ 24; others will "drive long

[3] Plaintiffs assert that some of their members have already altered their conduct in response to the possibility that Experior will enter the market, be used at cow feedlots near their homes, and somehow enter and contaminate the environment beyond the feedlots. *See, e.g.*, FAC ¶ 28 (alleging that a FWW member has "paused plans to purchase a paddleboard to use on waterways near her because of her concerns about direct exposure to Experior-contaminated water downstream from cattle feedlots"). Any injuries Plaintiffs' members have suffered in preparation for Experior's possible, future entry onto the market are necessarily self-inflicted and insufficient to establish standing. *See Clapper*, 568 U.S. at 416 (plaintiffs "cannot manufacture standing merely by inflicting harm on themselves based on their fear of hypothetical future harm that is not certainly impending").

distances . . . to purchase beef from suppliers that will not use Experior," *id.* ¶ 24; and still others will "pay premiums to purchase beef raised without Experior," *id.* ¶ 22.

Before Plaintiffs' members face any actual environmental harms from the use of Experior, however, their Amended Complaint makes clear that a lengthy and speculative chain of events must occur: Elanco would have to begin marketing Experior; feedlots near the waterways that Plaintiffs' members frequent would have to use Experior in their cow feed; those same feedlots would have to mismanage cow waste such that it could enter the environment beyond the feedlot; the cow waste from those feedlots would have to actually enter the environment; that waste would have to contain some amount of Experior; any residual amount of Experior that entered the waterways would have to reach the areas Plaintiffs' members use at times when they are using those areas; and any residual amount of Experior that entered the waterways would have to be capable of causing harm to the environment, humans, or animals. *See Ctr. for Biological Diversity*, 937 F.3d at 538 ("Courts cannot simply presume pollution discharged in one place will affect would-be plaintiffs everywhere."); *id.* at 540 (explaining that Article III requires a "temporal-nexus" linking alleged environmental injuries to challenged pollutant discharges). While it may be *possible* to satisfy all of these contingencies, "that speculation does not suffice" to establish Article III injury because "[s]tanding . . . is not an ingenious academic exercise in the conceivable[.]" *Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009) (quotation omitted) (attenuated chain of possibilities insufficient for procedural right claim).

The injuries Plaintiffs claim their members will suffer to avoid consuming beef containing residual levels of Experior are equally speculative. Plaintiffs allege that ALDF "has members and supporters who consume beef purchased from grocery stores and restaurants, which *can be* sourced from feedlots that *will likely* use Experior." FAC ¶ 22 (emphasis added). However, Plaintiffs offer no basis for how they know from which feedlots their local stores and restaurants source their beef and no basis supporting their claim that those feedlots are likely to use Experior. Moreover, Plaintiffs' assertions that their members "will drive long distances, sometimes two hours, to purchase beef from a supplier that will not use Experior," FAC ¶ 24; "will pay premiums to purchase beef raised without Experior, *id.* ¶ 22; and "will be unable to consistently find and

source beef that will be guaranteed to be raised without Experior," *id.* ¶ 22, are wholly speculative. Given that Experior is not on the market, Plaintiffs cannot know where Experior will be used, whether grocery stores near Plaintiffs' members will sell beef from cows raised with or without Experior, and how much more it will cost to buy beef from cows raised without Experior. Plaintiffs' speculation does not amount to any imminent injury, as required by Article III.

Nor do Plaintiffs plausibly allege any basis for asserting that they face a substantial risk that *all* of these events will come to pass—much less that their feared injuries are "certainly impending." *Driehaus*, 573 U.S. at 158; *see also Clapper*, 568 U.S. at 398 (courts "have been reluctant to endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment"); *cf. Cent. & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 700–01 (5th Cir. 2000) (allegations that bulk waste products disposed of in a landfill might "somehow" enter the town's water supply were insufficient to establish Article III injury). Plaintiffs' assertions that their members "need" to make changes to their recreational activities, diets, or purchasing habits in response to "fears" or "concerns" about Experior also miss the mark. A party invoking federal jurisdiction "cannot manufacture standing merely by inflicting harms on themselves based on their fears of hypothetical future harm that is not certainly impending." *Clapper*, 568 U.S. at 416. Such injuries "are not fairly traceable" to the agency action that Plaintiffs allege created their fear. *Id.* "[O]therwise, an enterprising plaintiff would be able to secure a lower standard for Article III standing simply by making an expenditure based on a nonparanoid fear." *Id.* Any self-imposed restrictions Plaintiffs' members have adopted in response to their fears and concerns about the potential, future use of Experior do not establish Article III injury. *See Los Angeles v. Lyons*, 461 U.S. 95 (1983), 107 n.8 ("It is the reality of the threat of [impending] injury that is relevant to the standing inquiry, not the plaintiff's subjective apprehensions.").

Second, Plaintiffs have not established *when* they will experience any actual injury as a result of FDA's approval of Experior. Plaintiffs acknowledge that Experior is not yet commercially available, *see* FAC ¶ 33, but allege that their members face "concrete and ongoing" harms because FDA has approved Experior and "actively allows it to be used and marketed." *id.*;

see also id. ¶ 26 (alleging that members will be harmed "when Experior is widely distributed in the marketplace" without providing any indication regarding when that will occur). Plaintiffs' members do not, however, face *imminent* harm merely because FDA allows the marketing and use of a drug that is not currently being marketed or used. The complete absence of allegations regarding when Experior will enter the market and when Plaintiffs' members would be adversely affected by Experior dictates that Plaintiffs have not plausibly alleged the type of imminent harm that Article III requires.

Third, Plaintiffs' allegations fall short of establishing that their members will recreate in areas affected by FDA's approval of Experior. "[T]o establish standing, plaintiffs must show that they 'use the area affected by the challenged activity and not an area roughly in the vicinity of' the activity." *Summers*, 555 U.S. at 499 (quoting *Lujan*, 504 U.S. at 566). Yet Plaintiffs do not say that their members intend to use any particular area where Experior will be used. Instead, Plaintiffs generally allege that their members live or recreate near feedlots that "*may* begin to use Experior" and speculate that there is a "*risk* that Experior will migrate from feedlots and contaminate the waterways and groundwater" that their members plan to use. FAC ¶¶ 20, 31 (emphases added). At most, Plaintiffs' allegations amount to a claim that they will use waterways in the vicinity of feedlots where Experior *might* (or might not) end up being used. These contentions are insufficient to establish that Plaintiffs face imminent injury due to FDA's approval of Experior. *See*, *e.g.*, *Ctr. for Biological Diversity*, 937 F.3d at 538 ("[P]etitioners cannot simply assert some interest somewhere within a large geographic area."); *cf. Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 667 (D.C. Cir. 1996) ("[A] court may not assume that the areas used and enjoyed by a prospective plaintiff will suffer all or any environmental consequences that the rule itself may cause.").

Because Plaintiffs have not plausibly alleged that they or their members face actual or imminent injuries the Court should dismiss Plaintiffs' claims for lack of standing.

B. Plaintiffs Have Not Shown That Their Alleged Injuries Are Fairly Traceable To FDA's Alleged NEPA Violations.

Along with adequately alleging an actual or imminent injury, a plaintiff also must show that any such alleged injuries are "fairly traceable" to the challenged action of the defendant, and not "the result of the independent action of some third party not before the court." *Tyler v. Cuomo*, 236 F.3d 1124, 1132 (9th Cir. 2000).[4] For that reason, where, as here, the plaintiff "is not the object of" the challenged "government action or inaction, 'standing is not precluded, but it is ordinarily substantially more difficult to establish.'" *Ctr. for Biological Diversity v. U.S. Dep't of Interior*, 563 F.3d 466, 477 (D.C. Cir. 2009) (quoting *Lujan*, 504 U.S. at 562). Here, the "choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict," *Lujan*, 504 U.S. at 562, sever the necessary chain of causation between FDA's NEPA review of its decision to approve Experior and the environmental injuries alleged in the Complaint.

Plaintiffs principally assert that their environmental injury flows from FDA's allegedly deficient NEPA review because Experior "will enter the environment through manure, and FDA fails to identify several known risks of environmental contamination due to CAFO manure management practices that will enable Experior to permeate the environment." FAC ¶ 149. *See also id*. ¶¶ 136–37; *id*. ¶ 74 (alleging discharges of animal feed that degrade water quality); ¶ 97 (alleging water pollution from CAFOs). But Plaintiffs concede that the allegedly injurious manure management and CAFO discharges are separately regulated by "state and federal law[s]" administered by agencies *other than* FDA, and over whom FDA has no control. *Id*. ¶ 154. These intervening authorities render "[t]he line of causation" from FDA's actions to CAFO discharges

[4] While Article III's "causation and redressability requirements are relaxed" in a NEPA case "*[o]nce a plaintiff has established an injury in fact*," *W. Watersheds Project v. Kraayyenbrink*, 632 F.3d 472, 485 (9th Cir. 2011) (emphasis added), Plaintiffs have failed to show a cognizable injury-in-fact in this case. *See supra* pp. 8–12. Regardless, even when "relaxed," causation remains "no less essential to the 'irreducible constitutional minimum' of standing." *Daniel v. Nat'l Park Serv.*, 891 F.3d 762, 767 (9th Cir. 2018).

too "attenuated" for standing purposes. *Wash. Envt'l Council v. Bellon*, 732 F.3d 1131, 1141 (9th Cir. 2013).[5]

In particular, Plaintiffs acknowledge EPA's primary statutory role enforcing the Clean Water Act's prohibition of the discharge of any pollutants into a waterway from any point source, including CAFOs. *See* FAC ¶ 154. Indeed, absent EPA's issuance of a permit authorizing and regulating the discharge of such a pollutant to minimize or prevent environmental damage, the Clean Water Act prohibits such discharges. *See* 33 U.S.C. § 1311(a); *id*. § 1342(a); *id.* § 1362(14) (defining "concentrated animal feeding operation[s]" as point sources under the Clean Water Act). EPA has accordingly issued regulations governing CAFO discharges to minimize potential impacts on water quality and public health. *See*, *e.g.*, 40 C.F.R. §§ 412.1, *et seq*. (describing, among other things, best management practices for management of manure from a variety of farm animals). In short, "the pollutants that will cause [Plaintiffs'] assumed injuries" are traceable to EPA's regulation of CAFO discharges, not FDA's approval of Experior. *Ctr. for Biological Diversity*, 937 F.3d at 544. Article III causation is not satisfied where, as here, the allegedly injurious action is taken "pursuant to some other authority or in violation of law" enforced by another agency. *Id*.

Plaintiffs' allegation that "EPA notoriously underregulates the CAFO industry," FAC ¶ 154, does not shift responsibility for CAFO discharges from EPA to FDA or cause Plaintiffs' alleged environmental injuries to result from FDA's alleged failure to consider this EPA "underregulat[ion]" in its NEPA analysis. Rather, "it is reasonable for an agency to presume that other agencies enforce applicable requirements according to the law." *Okanogan Highlands All. v. Williams*, No. 97-cv-806-JE, 1999 WL 1029106, at *6 (D. Or. Jan. 12, 1999). In other words,

[5] Plaintiffs' related allegations that approval of Experior injures their members because it "is likely to increase cow herd size and density at feedlots, and . . . could encourage construction of new feedlots," Compl., ¶ 34, are too speculative to establish causation. *See*, *e.g.*, *Clapper*, 568 U.S. at 414 (holding that "speculative chain of possibilities does not establish that injury . . . is fairly traceable" to challenged government action). Plaintiffs allege no facts to support their assumption that approval of Experior will cause CAFOs to increase the density of herds or construct new facilities. *See Lujan*, 541 U.S. at 562 (explaining that it is plaintiff's burden to demonstrate "facts showing that [the unfettered] choices [of third parties] have been or will be made in such manner as to produce causation and permit redressability of injury").

FDA may reasonably "base its evaluation of environmental impacts on the assumption that other specialized agencies with jurisdiction will enforce" laws and regulations governing CAFO discharges. *Id*. at *4 (citing *No GWEN All. of Lane Cty., Inc. v. Aldridge*, 855 F.2d 1380, 1386–87 (9th Cir. 1988)), *see also U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001) ("[A] presumption of regularity attaches to the actions of Government agencies."); *Gulf Restoration Network v. Bernhardt*, No. 18-cv-1674-RBW, 2020 WL 1930470, at *11 (D.D.C. April 21, 2020) (holding that agency's NEPA analysis reasonably relied on another agency's enforcement of its regulatory authority over allegedly injurious activities).

Having "hinge[d]" their NEPA claim on the independent decisions of CAFOs and the independent exercise of regulatory authority by EPA, *Lujan*, 504 U.S. at 562, Plaintiffs have failed adequately to connect their alleged injuries to FDA's decisions to approve Experior, or FDA's corresponding NEPA review of the potential effects that approval may have on the environment. The Court should therefore dismiss Plaintiffs' NEPA claim for lack of Article III standing.

C. Plaintiffs Have Not Shown That Their Alleged Injuries Are Likely To Be Redressed By Relief From This Court.

Redressability examines the "connection between the alleged injury and the judicial relief requested." *Allen v. Wright*, 468 U.S. 737, 753 n.19 (1984). The mere fact that a court has the power to issue the relief requested in a Complaint is irrelevant absent direct redress of the plaintiff's asserted injuries. In other words, "[r]elief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court." *Steel Co.*, 523 U.S. at 107.

In the NEPA context, a plaintiff must show that "the relief requested—that the agency follow the correct procedures—may influence that agency's ultimate decision of whether to take or refrain from taking a certain action." *Salmon Spawning v. Gutierrez*, 545 F.3d at 1226–27 (9th Cir. 2008). Although relaxed in the NEPA context, the redressability requirement is "not toothless in procedural injury cases." *Id.* at 1227. Among other things, a procedural injury is not redressable where, even if the plaintiff prevails, a party not before the Court remains free to engage in the allegedly injurious actions and the plaintiff cannot show that the third-party would refrain from taking those actions as a result of the requested judicial relief against the agency

defendant. *See Lujan*, 504 U.S. at 562; *see also, e.g.*, *Levine v. Vilsack*, 587 F.3d 986, 995 (9th Cir. 2009); *Nuclear Info. & Res. Serv. v. Nuclear Reg. Comm'n*, 457 F.3d 941, 955 (9th Cir. 2006) (no redressability where another agency's rules had the same effect as the challenged agency action).

Here, redressability is lacking because of the existence of third parties' intervening "broad and legitimate discretion the courts cannot presume either to control or to predict." *Lujan*, 504 U.S. at 562 (quotation omitted). Even if the Court issues an order remanding FDA's approval decisions for further NEPA analysis, as explained above EPA holds regulatory authority over the CAFO manure management and discharges responsible for Plaintiffs' alleged injuries. *See supra* pp. 14–15. On remand, FDA remains entitled reasonably to assume that EPA fulfills its statutory and regulatory obligations, *see supra* pp. 14–15, and the Amended Complaint alleges no facts suggesting that FDA would decide otherwise, *see Lujan*, 541 U.S. at 562. Given EPA's intervening authority and FDA's legitimate reliance on EPA to fulfill its statutory role as the primary regulator of CAFO pollution, Plaintiffs have not shown that the alleged injuries on their NEPA claim are redressable in this litigation.[6]

II. THE COURT SHOULD DISMISS, OR IN THE ALTERNATIVE, STAY THIS SUIT DUE TO PLAINTIFFS' FAILURE TO EXHAUST MANDATORY ADMINISTRATIVE REMEDIES.

Plaintiffs' claims that FDA violated NEPA and the FDCA are brought pursuant to the APA. *See*, *e.g.*, FAC, Claims for Relief ¶¶ 1–26; *Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1353 n.13 (9th Cir. 1994) ("NEPA does not provide a private cause of action for violations of its provisions."); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1287 (C.D. Cal. 2008) ("[N]o private right of action exists to redress alleged violations of the FDCA.").

[6] This is not to say that Plaintiffs have no way of vindicating their environmental claims. To the extent Plaintiffs believe EPA is not fulfilling its statutory obligations regarding regulation of CAFOs, Plaintiffs may seek judicial review of EPA's actions (or omissions) directly. What Plaintiffs may *not* do is mount a back-door challenge to those EPA actions by seeking review of a different agency's decisionmaking. *See, e.g.*, *Lujan*, 541 U.S. at 561–62.

The APA, in turn, requires exhaustion of mandatory administrative remedies prior to filing suit. Because Plaintiffs have not exhausted the citizen petition administrative remedy mandated by FDA regulations, Plaintiffs' claims should be dismissed, or in the alternative stayed, to allow Plaintiffs to pursue the prescribed citizen petition process and allow the agency "to exercise its expertise over the subject matter" asserted in Plaintiffs' claims. *Buckingham v. Sec'y of USDA*, 603 F.3d 1073, 1080 (9th Cir. 2010) (quoting *United Farm Workers v. Ariz. Agric. Emp't Relations Bd.*, 669 F.2d 1249, 1253 (9th Cir. 1982)). *See also Ctr. for Food Safety*, 696 F. App'x at 303–04.

A. FDA Regulations And The APA Require Exhaustion Of The Agency's Mandatory Citizen Petition Administrative Remedy.

Under the doctrine of exhaustion of administrative remedies, "no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted." *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50–51 (1938). "Broadly speaking, the doctrine of exhaustion of administrative remedies 'serves the twin purposes of protecting administrative agency authority and promoting judicial efficiency.'" *Ass'n of Flight Attendants-CWA, AFL-CIO v. Chao*, 493 F.3d 155, 158 (D.C. Cir. 2007) (quotation omitted). To those ends, "[e]xhaustion gives an agency an opportunity to correct its own mistakes . . . before it is haled into federal court, and it discourages disregard of [the agency's] procedures." *Woodford v. Ngo*, 548 U.S. 81, 89 (2006) (citation omitted).

Section 704 of the APA codifies this bedrock common law exhaustion doctrine. *See* 5 U.S.C. § 704; *Bowen v. Massachusetts*, 487 U.S. 879, 902 (1988) ("the primary thrust of § 704 was to codify the exhaustion requirement"); *Shawnee Trail Conservancy v. USDA*, 222 F.3d 383, 388–89 (7th Cir. 2000) ("The requirement of administrative exhaustion is a traditional common law doctrine that has now been codified in section 10(c) of the APA, 5 U.S.C. § 704."). In "strengthen[ing] . . . the principle requiring the exhaustion of administrative remedies," *Fed. Power Comm'n v. Colo. Interstate Gas Co.*, 348 U.S. 492, 499–500 (1955), the APA mandates exhaustion "to the extent that it is required by statute or by agency rule as a prerequisite to judicial review," *Darby v. Cisneros*, 509 U.S. 137, 153 (1993). Thus, a plaintiff generally must exhaust

"all administrative remedies expressly prescribed by statute or agency rule" before seeking judicial review pursuant to the APA. *Id*. at 146.

With respect to Plaintiffs' challenges to FDA's approval of Experior, FDA regulations permit any member of the public to challenge any agency action, including the approval of a NADA, via a citizen petition. The citizen petition regulation broadly permits any interested person to "petition the Commissioner to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). Such "[a]dministrative action" includes "every act . . . involved in the administration of any law by the Commissioner." 21 C.F.R. § 10.3(a). Agency regulations further require a "final administrative decision" on such petitions before a party may seek judicial review, providing:

> A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on *a petition submitted under § 10.25(a)* . . . before any legal action is filed in a court complaining of the action or failure to act.

21 C.F.R. § 10.45(b) (emphases added). In the meantime, "[a]n interested person may request the Commissioner to stay the effective date of any administrative action," including a stay "for an indefinite time period." 21 C.F.R. § 10.35(b).

Taken together, FDA's regulations require Plaintiffs to exhaust the citizen petition process set out in 21 C.F.R. § 10.25(a) before filing suit. Only then has FDA taken "final agency action" on the issues raised by the Plaintiffs that is "reviewable in the courts under 5 U.S.C. 701 *et seq*." 21 C.F.R. § 10.45(d). *See also Darby*, 509 U.S. at 146 ("When an aggrieved party has exhausted all administrative remedies expressly prescribed by statute or agency rule, the agency action is 'final for the purposes of [§ 704]' and therefore 'subject to judicial review' under the first sentence [of § 704].").

B. Plaintiffs' Claims Should Be Dismissed Because Plaintiffs Have Not Exhausted FDA's Mandatory Administrative Remedy.

The Amended Complaint does not allege (nor could it allege) that Plaintiffs have exhausted the FDA's citizen petition procedure before filing this suit. Because Plaintiffs have not completed the FDA's mandatory citizen petition process, they have not satisfied the APA's

exhaustion requirement, and their challenge "is not directly appealable" to the courts. *Clouser v. Espy*, 42 F.3d 1522, 1532 (9th Cir. 1994) (applying Forest Service mandatory exhaustion provisions). Rather, "exhaustion should be required before an aggrieved party may seek federal court review"—a "requirement that plaintiffs have not satisfied" in this case. *Id*.

Indeed, "[t]he necessity for prior administrative consideration . . . is apparent where, as here," resolution of the issues presented "calls for the application of technical knowledge and experience not usually possessed by judges." *Fed. Power Comm'n*, 348 U.S. at 501. *See also Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 654 (1973) ("Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand."). Here, Plaintiffs raise issues of drug safety and effectiveness, and the health of humans and animals. *See supra* pp. 3–5. These issues are core to FDA's mission under the FDCA and raise scientific and technical questions within FDA's expertise. *See*, *e.g.*, *ThermoLife Int'l, LLC v. Gaspari Nutrition, Inc.*, 648 F. App'x 609, 612 (9th Cir. 2016) (recognizing that "the FDCA protects public health by relying on the FDA's expertise"); *Tri-Bio Labs, Inc. v. United States*, 836 F.2d 135, 142 (3d Cir. 1987); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1376 (9th Cir. 1983).

Moreover, the relief Plaintiffs seek from this Court—vacatur of FDA's approval of Experior, and an injunction against use of Experior pending completion of a renewed approval procedure on remand—would be available through the administrative citizen petition process. Animal and human health concerns—if adequately demonstrated by Plaintiffs through a citizen petition—would permit FDA to suspend or withdraw approval of Experior. *See* 21 U.S.C. § 360b(e)(1); *id*. § 360b(i); 21 C.F.R. § 514.115(a), (b) (authorizing FDA to suspend or withdraw approval of a NADA if, among other things, "[e]xperience or scientific data" or "[n]ew evidence" show that the drug is unsafe or poses "an imminent hazard to the health of man or of the animals" using the approved drug or feed). Likewise, FDA regulations make clear that post-approval comments on environmental aspects of the NADA also "can form the basis for the Agency to consider beginning an action to withdraw the approval . . . ." 21 C.F.R. § 25.52(b). Upon

withdrawal of approval of the NADA, the regulation authorizing use of the drug "shall be revoked." 21 C.F.R. § 514.115(e).

That ALDF filed a petition with FDA to *stay approval* of Experior does not, as Plaintiffs claim, "exhaust[] administrative remedies," FAC, First Claim for Relief, ¶ 4 (citing 21 C.F.R. § 10.45(c)), and create a "final agency action subject to judicial review under the APA," *id*. ¶ 6 (citing 5 U.S.C. § 704). While ALDF filed a petition for a stay pursuant to 21 C.F.R. § 10.35(b), the Amended Complaint is silent as to *any* action taken by Plaintiffs to comply with the citizen petition requirement. Exhaustion of Plaintiffs' present claims requires "a [citizen] petition submitted under § 10.25(a)" "before any legal action is filed in a court complaining of the action or failure to act." 21 C.F.R. § 10.45(b). *See supra* pp. 5–6.

To the extent that ALDF's Stay Petition implicates exhaustion, that petition may exhaust a claim in this Court "*requesting a stay of administrative action*." 21 C.F.R. § 10.45(c) (emphasis added). But Plaintiffs request no such remedy. Rather, Plaintiffs ask this Court to "[v]acate FDA's decision to approve Experior unless and until it complies with the FDCA, NEPA, and the APA"; and (2) "[i]ssue preliminary and permanent injunctive relief barring the use of Experior until FDA complies with the FDCA, NEPA, and the APA." FACT, Request for Relief, ¶¶ 3–4. Plaintiffs therefore ask this Court to effect a withdrawal of FDA's decision approving Experior and a corresponding bar against Experior's use pending FDA's further review on remand—the remedies available through the citizen petition process. *See supra* pp. 17–18. As the Ninth Circuit confirmed three years ago in ALDF's prior challenge to FDA's approval of a different drug that is also approved to be administered in feed, such claims "[r]equir[e]" Plaintiffs "*to file a citizen petition*." *Ctr. for Food Safety*, 696 F. App'x at 303 (emphasis added). *See also Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 358 F. App'x 179, 181 (D.C. Cir. 2009) (explaining that FDA regulations "explicitly require" exhaustion of the citizen petition process before an interested person may seek judicial review of the agency's action).

Moreover, "[a] reviewing court usurps the agency's function when it sets aside the administrative determination upon a ground not theretofore presented." *Unemployment Comp. Comm'n of Territory of Alaska v. Aragan*, 329 U.S. 143, 155 (1946). *See also United States v.*

L.A. Tucker Truck Lines, Inc., 344 U.S. 33, 37 (1952) ("[C]ourts should not topple over administrative decisions unless the administrative body not only has erred, but has erred against objection made at the time appropriate under its practice."). Although ALDF's Stay Petition raised various challenges to FDA's approval of Experior, it did not allow "the expert agency [Congress] created," *Hynson, Westcott & Dunning*, 412 U.S. at 627, "an opportunity to correct any mistakes that may have occurred during the proceeding, thus avoiding unnecessary or premature judicial intervention," *Buckingham*, 603 F.3d at 1080 (citation omitted). To the contrary, ALDF's Stay Petition merely requested a stay of the Experior approval, not (as Plaintiffs seek here) a substantively different outcome regarding that approval decision. Moreover, ALDF's Stay Petition presented only brief, vague, and often "unsupported" contentions regarding the state of science regarding Experior's effects on human health, animal health, and the environment. *See supra* pp. 5–6. The Amended Complaint is no different, *see*, *e.g.*, FAC ¶ 137 (alleging that unidentified "[s]tudies indicate that animals fed Experior experienced poor appetite and other gastrointestinal issues"), and further underscores the necessity of directing Plaintiffs' claims to the citizen petition procedure mandated by FDA's regulations.

The other two Plaintiffs—Food & Water Watch and Food Animal Concerns Trust—have an even weaker claim to exhaustion, having failed to file *anything* regarding their claims at the FDA. The Amended Complaint speaks only to ALDF's Stay Petition and does not mention agency submissions by the remaining Plaintiffs. As a result, those Plaintiffs have not plausibly alleged that they have complied with the exhaustion requirement.

In short, ALDF chose to pursue an administrative remedy that does not exhaust the claims asserted in the Amended Complaint, and the other Plaintiffs chose not to pursue any administrative remedies whatsoever. The APA's exhaustion requirement, however, directs Plaintiffs to pursue the precise remedy prescribed by FDA's rules, "which means using all steps that the agency holds out, and doing so *properly*[.]" *Woodford*, 548 U.S. at 90 (citation and quotation omitted)). "Because exhaustion requirements are designed to deal with parties who do not want to exhaust, administrative law creates an incentive for these parties to do what they would otherwise prefer not to do, namely, to give the agency a fair and full opportunity to

adjudicate their claims." *Id*. Dismissal of the Amended Complaint is therefore warranted for Plaintiffs' failure properly to exhaust FDA's prescribed citizen petition procedure.

C. In The Alternative, A Stay Of Proceedings Is Appropriate To Allow Plaintiffs To Exhaust The Mandatory Citizen Petition Remedy.

Although Plaintiffs' failure to exhaust their administrative remedies supports dismissal, in these circumstances, the Court may nevertheless "stay further proceedings to allow [Plaintiffs] to comply with the FDA's citizen petition requirement." *Ctr. for Food Safety*, 696 F. App'x at 304. Such a stay "prevent[s] the premature interference with agency processes so that the agency may function efficiently . . .[,] afford the parties and the courts the benefit of its experience and expertise, and . . . compile a record which is adequate for judicial review." *Id*. at 303 (quoting *Tamosaitis v. URS Inc.*, 781 F.3d 468, 478 (9th Cir. 2015)). Accordingly, in the event that the Court declines to dismiss the Amended Complaint for failure to exhaust, Elanco respectfully requests that the Court stay this case pending Plaintiffs' exhaustion of the citizen petition requirement.

III. PLAINTIFFS' FIRST CLAIM FOR RELIEF SHOULD BE DISMISSED FOR FAILURE PROPERLY TO REQUEST RELIEF PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 8 AND 12(b)(6).

To the extent that Plaintiffs' First Claim for Relief challenging FDA's denial of ALDF's Stay Petition, *see* FAC, First Claim for Relief, ¶¶ 1–7, cannot be further exhausted before the agency, that claim nevertheless should be dismissed because the Complaint fails to request any relief for FDA's allegedly erroneous denial.

Plaintiffs' First Claim for Relief appears primarily directed at establishing exhaustion for the entire Amended Complaint and a final agency action subject to judicial review. *See id.*, First Claim for Relief, ¶¶ 1–7 (alleging that denial of ALDF's Stay Petition "is final agency action subject to judicial review"). *But see supra* pp. 18–22 (explaining that ALDF's Stay Petition did not exhaust the required administrative remedies). Indeed, neither the First Claim for Relief nor Plaintiffs' Request for Relief seeks an order setting aside FDA's denial of ALDF's Stay Petition, or granting a stay of the effective date of FDA's approval of Experior as requested in ALDF's Stay Petition. *See* Stay Petition, *supra* n.1, at 1. Rather, the Complaint requests vacatur of FDA's

decision approving Experior, and corresponding injunctive relief barring use of Experior while FDA addresses the vacated approval. *See id.*, Relief Requested, ¶¶ 3–4. Such remedies target FDA's allegedly erroneous *approval* of Experior in the first instance, not the *denial of a stay* of the approval's effective date.

Viewed as a whole, Plaintiffs' First Claim for Relief lacks a connected remedial request. Federal Rule of Civil Procedure 8 requires a complaint to "clearly and concisely" set out "what legal theories plaintiff relies upon, and what relief plaintiff seeks *as to each claim*." *Azizi v. United States*, No. 15-cv-07456-CAS, 2015 WL 6755193, at *3 (C.D. Cal. Nov. 4, 2015) (emphasis added). Likewise, under Federal Rule of Civil Procedure 12(b)(6), "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal*, 556 U.S. at 679 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). Plaintiffs' failure to seek a remedy directed at denial of ALDF's Stay Petition therefore warrants dismissal. *See*, *e.g.*, *Azizi*, 2015 WL 6755193, at *3 (dismissing complaint without prejudice); *Hong v. Read*, No. 19-cv-00086-RGK, 2020 WL 4342539, at * n.1 (C.D. Cal. April 3, 2020) (explaining that a complaint must "contain a 'short and plain statement' of each claim for relief 'showing that [plaintiff] is entitled to relief' (quoting Fed. R. Civ. P. 8(a), (d)); *Finn v. City of Boulder City*, No. 14-cv-1834-JAD, 2015 WL 2186497, at *2 (D. Nev. May 6, 2015) ("Each claim should be set out in a separate cause of action that contains all facts supporting its essential elements and states the specific relief requested."). *Cf. Lojas v. Washington*, 347 F. App'x 288, 290 (9th Cir. 2009) (affirming dismissal of § 1983 claim for failure to request prospective injunctive relief cognizable on such a claim).[7]

[7] Plaintiffs' request for injunctive relief, moreover, is superfluous in this case. Plaintiffs claim that FDA's approval of Experior was arbitrary and capricious in violation of the APA and that vacatur of the approval is therefore warranted. *See*, *e.g.*, FAC First Claim for Relief, ¶ 7; *id.*, Second Claim for Relief, ¶ 13, *id.*, Third Claim for Relief, ¶ 25, *id.*, Relief Requested, ¶ 3. Because neither a new animal drug nor animal feed containing a new animal drug may be used absent FDA approval, *see* 21 U.S.C. § 360b(a)(1)–(2); *id.* § 360b(b)(1) (requiring new animal drug applicant to submit reports of investigations "to show whether or not such drug is safe and effective for use"), the FDCA and a vacatur order would result in the ban on use of Experior that Plaintiffs' requested injunctive relief seeks. Plaintiffs' request for an injunction is therefore illusory. *See N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012) ("It was quite anomalous to issue an injunction. When a district court reverses agency action and determines

Even assuming that Plaintiffs' challenge to the denial of ALDF's Stay Petition satisfies the pleading requirements of Rules 8 and 12(b)(6), because Plaintiffs' other unexhausted claims challenge the underlying approval of Experior, in the interest of efficiency the Court should likewise stay Plaintiffs' First Claim pending exhaustion of Plaintiffs' remaining claims.

CONCLUSION

For the foregoing reasons and those set forth in the Federal Defendants' brief, Elanco respectfully requests that this Court dismiss the Plaintiffs' claims or, in the alternative, stay this action pending Plaintiffs' exhaustion of FDA's mandatory citizen petition procedure.

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Respectfully submitted,

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that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal.").